UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA CIVIL ACTION NO.

UNITED THERAPEUTICS CORPORATION,

Plaintiff,

v.

LIQUIDIA TECHNOLOGIES, INC.,

Defendant.

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff United Therapeutics Corporation ("UTC"), by its undersigned attorneys, brings this action for patent infringement and declaratory judgment against Defendant Liquidia Technologies, Inc. ("Liquidia"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 11,357,782 ("the '782 patent") under the patent laws of the United States, 35 U.S.C. §§ 101 *et seq.*, including § 271(b)–(c), and an action for declaratory judgment of infringement pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, *et seq.*, arising from Liquidia's unauthorized development, manufacturing, commercial marketing, distribution, offers for sale, sales and/or use of Yutrepia[™] (treprostinil) inhalation powder for the treatment of pulmonary hypertension ("PH"), and seeking a judicial declaration that Liquidia will infringe the '782 patent imminently and to prevent Liquidia from any future infringement,

as detailed herein. A true and correct copy of the '782 patent is attached hereto as **Exhibit A**.

2. UTC currently markets Tyvaso[®] (treprostinil) inhalation solution, which was approved by the FDA in 2009, and Tyvaso DPI[®] (treprostinil) inhalation powder, which was approved by the FDA in 2022. Tyvaso DPI[®] is the first marketed dry powder formulation of treprostinil in the United States. Liquidia has tentative approval for Yutrepia[™], a second dry powder formulation of treprostinil.

THE PARTIES

- 3. UTC is a corporation organized and existing under the laws of the State of Delaware and having a principal place of business and corporate headquarters at 55 T.W. Alexander Drive, Research Triangle Park, North Carolina 27709. UTC is a biotechnology company focused on the development and commercialization of products designed to address the needs of patients with chronic and life-threatening conditions. UTC continues to research and develop treatments for cardiovascular and pulmonary diseases, pediatric cancers, and other orphan diseases.
- 4. Upon information and belief, Liquidia is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 419 Davis Drive, Suite 100, Morrisville, North Carolina 27560.

JURISDICTION AND VENUE

- 5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
- 6. This Court has personal jurisdiction over Liquidia because, among other things, Liquidia has a principal place of business in North Carolina.
- 7. This Court also has personal jurisdiction over Liquidia because Liquidia has publicly stated its preparation for commercialization and intent to engage in commercializing its Yutrepia[™] product throughout the United States as soon as possible without any limitation. Upon information and belief, Liquidia will manufacture, market, store, distribute, sell and/or offer to sell Yutrepia[™] throughout the United States, including in North Carolina, and will derive substantial revenue therefrom.
- 8. This Court also has personal jurisdiction over Liquidia because there is a direct connection between UTC's patent infringement claims and Liquidia's significant presence and activities in North Carolina, which give rise to UTC's claims.
- 9. This Court also has personal jurisdiction over Liquidia because Liquidia has availed itself of the legal protections of North Carolina by, among other things, selecting North Carolina as the place of business for itself and/or subsidiaries and consenting to jurisdiction by participating in lawsuits and/or filing complaints in lawsuits that are filed

in this Court. See Liquidia Techs., Inc. v. United Therapeutics Corp., C.A. 1-25-cv-00299 (M.D.N.C.).

10. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) because Liquidia resides in this District, including by maintaining its corporate headquarters in this District, and because Liquidia conducts business within this District, including, upon information and belief, a substantial part of the events that give rise to UTC's claims.

BACKGROUND

I. UTC'S TYVASO DPI® AND THE '782 PATENT

11. Pulmonary hypertension ("PH") is a debilitating and often fatal disease characterized by elevated blood pressure in the lungs. There are different varieties of PH, including pulmonary arterial hypertension ("PAH") and pulmonary hypertension associated with interstitial lung disease ("PH-ILD"). PAH is a rare disease affecting the pulmonary vasculature and involving high pressure in the pulmonary arteries, which increases strain on the right ventricle of the heart, which can lead to heart failure and death. PH-ILD is a complex, progressive disease where a patient's PH is caused by interstitial lung disease ("ILD"), an umbrella term for a broad set of disorders characterized by fibrosis or inflammation of the space between the lungs and the pulmonary vasculature which is critical for gas exchange.

¹ In light of the commonality parties and products and overlapping subject matter regarding the inhaled dry powder administration of treprostinil to treat pulmonary hypertension, UTC files this as a related case to *Liquidia Techs.*, *Inc. v. United Therapeutics Corp.*, C.A. 1:25-cv-00299 (M.D.N.C.). UTC will confer with Liquidia on a joint motion to consolidate the two actions at an appropriate time.

- 12. On May 23, 2022, the FDA approved UTC's New Drug Application No. 214324 for Tyvaso DPI[®] (treprostinil) inhalation powder for the treatment of PAH and PH-ILD, which UTC markets and sells under the registered trademark Tyvaso DPI[®].
- 13. The '782 patent, entitled "Treprostinil administration by inhalation," was duly and legally issued by the United States Patent and Trademark Office on June 14, 2022. The named inventors are Horst Olschewski, Robert Roscigno, Lewis J. Rubin, Thomas Schmehl, Werner Seeger, Carl Sterritt, and Robert Voswinckel.
- 14. UTC is the lawful owner of the '782 patent by assignment of all right, title, and interest in and to the '782 patent, including the right to bring infringement suits thereon.
- 15. The '782 patent describes, *inter alia*, a method for treating pulmonary hypertension by administering a powder formulation of treprostinil via oral inhalation with a dry powder inhaler. *See generally* Ex. A.

16. Claim 1 of the '782 patent recites:

A method of treating pulmonary hypertension comprising: providing an inhalation device for treating pulmonary hypertension in a human suffering from pulmonary hypertension comprising a powder formulation of treprostinil or a pharmaceutically acceptable salt thereof and a dry powder inhaler configured to administer single event dose of the powder formulation comprising treprostinil or a pharmaceutically acceptable salt thereof, wherein the single event dose comprises at least 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 3 breaths, wherein the dry powder inhaler is configured to administer the entire single event dose in less than 5 minutes with at least 5 micrograms of treprostinil or a pharmaceutically acceptable salt thereof being inhaled per breath through coordinated actuation of the dry powder inhaler with each breath, and administering to a human suffering from pulmonary hypertension with the dry powder inhaler the single event dose comprising at least 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof in 1 to 3 breaths, wherein the human administers the

entire single event dose with the dry powder inhaler in less than 5 minutes by inhaling at least 5 micrograms of treprostinil or a pharmaceutically acceptable salt thereof per breath by coordinating one actuation of the dry powder inhaler for each separate breath, and wherein administration of an additional single event dose in the same manner occurs at least 3 hours later.

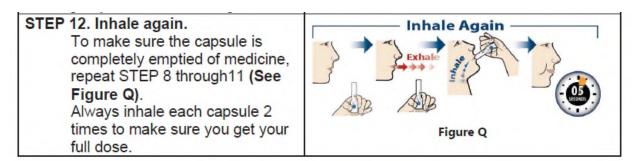
- 17. Upon information and belief, Liquidia had knowledge of the '782 patent since at least June 14, 2022, when the patent was issued.
- 18. Upon information and belief, Robert Roscigno, one of the named inventors of the '782 patent, was an employee at Liquidia at late as June 2020.

II. YUTREPIA™ AND LIQUIDIA'S INFRINGING ACTIVITY

A. Yutrepia[™]

- 19. Upon information and belief, Liquidia is the owner of NDA No. 213005 for Yutrepia[™] (treprostinil) inhalation powder, which was filed under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act and pursuant to 21 U.S.C. § 355(b)(2).
- 20. On November 26, 2024, Liquidia filed a copy of its label for Yutrepia[™], with a revision date of 08/2024, and the accompanying Instructions for Use, in *Liquidia Techs.*, *Inc. v. U.S. Food and Drug Admin. et al.*, No. 1:24-cv-02428-TJK, ECF No. 78-2 (D.C. Nov. 26, 2024) (hereinafter the "Prescribing information"). A true and correct copy of the Label and Instructions for Use is attached hereto as **Exhibit B**.
- 21. According to the Prescribing Information, Yutrepia[™] will be indicated for the treatment of "[p]ulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability" and "[p]ulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability." Ex. B at 1.

- 22. According to the Prescribing Information, Yutrepia[™] is an inhalation dry powder formulation with treprostinil as the active ingredient. *See*, *e.g.*, Ex. B at 2–3, 7–8, 15, 17.
- 23. The Prescribing Information states that "YUTREPIA contains treprostinil sodium." Ex. B at 7.
- 24. The Prescribing Information states that "YUTREPIA inhalation powder contained in a capsule is intended for oral inhalation." *Id.* The Prescribing Information further states that "[t]he accompanying inhalation device for delivery of YUTREPIA is a disposable plastic device used to inhale the dry powder contained in the HPMC capsule." *Id.*
- 25. According to the Prescribing Information and Instructions for Use, Yutrepia[™] is administered via coordinated actuation of an accompanying inhalation device configured to administer a single dose of treprostinil over two breaths. Ex. B at 2–4, 7, 18, 23–24.



Ex. B at 24.

26. The Prescribing Information states that Yutrepia[™] is available in capsules containing 26.5 mcg, 53 mcg, 79.5 mcg, and 106 mcg of treprostinil. Ex. B at 2–3, 7–8,

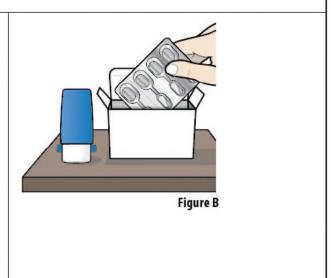
- 15, 17, 19. Inhalation of these capsule doses results in a dose delivered ranging from 15.1 mcg to 75.7 mcg. *See id.* at 7–8.
- 27. The Prescribing Information states that "[i]n patients naive to treprostinil, therapy should begin with 26.5 mcg 3 to 5 times per day, in 2 breaths based on patient response." Ex. B at 2–3. The Prescribing Information further states that "[p]atients transitioning from treprostinil inhalation solution (Tyvaso), can begin YUTREPIA therapy 3 to 5 times per day, in 2 breaths" with a dosage of 26.5 mcg, 53 mcg, 79.5 mcg, 106 mcg, 132.5 mcg, or 159 mcg of treprostinil, depending on the patient's current Tyvaso DPI® dose. *Id*.
- 28. The Instructions for Use state that each Yutrepia[™] capsule "must be inhaled within 5 minutes." *See* Ex. B at 17, 19.

Preparing to use YUTREPIA

The capsule must be inhaled within 5 minutes of opening the blister card. Ensure all supplies are gathered and you are familiar with the use of the product prior to opening the card.

STEP 1. Gather your supplies.

- Place your YUTREPIA carton on a clean, dry surface.
- Remove the inhaler and foil blister cards from the carton (See Figure B).



Ex. B at 19.

29. The Prescribing Information states that Yutrepia[™] "should be administered 3 to 5 times per day" with a "minimum recommended dosing interval of four hours." Ex. B. at 1–3.

B. Liquidia Obtains Tentative FDA Approval of Yutrepia[™] and Announces Plans to Imminently Launch

- 30. On August 19, 2024, Liquidia announced that the FDA tentatively approved Yutrepia[™] for treatment of adults with PAH and PH, with final approval not to be awarded until the expiration of UTC's 3-year regulatory exclusivity for UTC's Tyvaso DPI[®] on May 23, 2025. *See* Exhibit C, a true and correct copy of *U.S. FDA Grants Tentative Approval of YUTREPIA*[™] (treprostinil) Inhalation Powder for Patients with Pulmonary Arterial Hypertension (PAH) and Pulmonary Hypertension Associated with Interstitial Lung Disease (PH-ILD), Liquidia (Aug. 19, 2024), https://www.liquidia.com/news-release-details/us-fda-grants-tentative-approval-yutrepiatm-treprostinil.
- 31. On March 28, 2025, Liquidia announced that the FDA accepted a resubmission for Yutrepia[™], that the FDA planned to issue its final decision on drug approval on May 24, 2025. **Exhibit D**, a true and correct copy of *Liquidia Corporation Announces FDA Acceptance of New Drug Application Resubmission for YUTREPIA* [™] (*treprostinil*) *Inhalation Powder*, Liquidia (Mar. 28, 2025), https://www.liquidia.com/news-releases/news-release-details/liquidia-corporation-announces-fda-acceptance-new-drug.
- 32. Upon information and belief, Liquidia will and/or has manufactured, imported, prepared, acquired, and/or stockpiled commercial batches of treprostinil API and

Yutrepia[™] for release, use, and sale upon final FDA approval, which is anticipated to be effective on May 24, 2025.

- 33. For example, at an April 2025 Needham & Co. Healthcare Conference, Liquidia Chief Executive Officer Roger Jeffs and Chief Financial Officer Mike Kaseta discussed the impending launch of the Yutrepia[™] product. *See* Exhibit E, a true and correct Transcript of Liquidia (LQDA) Gears Up for FDA Approval of Yutrepia |Needham 2025, YOUTUBE, https://www.youtube.com/watch?v=_y5it02b88E. During the conference, Jeffs stated that Liquidia was "preparing to vigorously enter ... the market at full speed" and was only "45 days away from [the FDA's final approval] date of May 24th." *Id.* at 4:9–20. Jeffs also stated that Liquidia is "going to begin a directed transition study where [Liquidia] take[s] patients from the incumbent brand, Tyvaso and Tyvaso DPI, and begin[s] to transition them to Yutrepia." *Id.* at 5:11–15.
- 34. Liquidia's manufacturing, importing, preparing, acquiring, and/or stockpiling is not solely for uses reasonably related to the development and submission of information for approval of Liquidia's § 505(b)(2) application, covering Yutrepia[™]. Therefore, it does not qualify for the safe harbor in 35 U.S.C. § 271(e)(1).
- 35. Liquidia has coordinated with respect to the manufacture, import, storage, and distribution of Liquidia's Yutrepia[™] product, and will continue to do so, in substantial and meaningful preparation for immediate launch of Yutrepia[™] upon final FDA approval.
- 36. Liquidia is currently running an Open-Label Prospective Multicenter Study to Evaluate Safety and Tolerability of Dry Powder Inhaled Treprostinil in Pulmonary

Hypertension, referred to as the ASCENT trial. *See* Exhibit F, a true and correct copy of *Liquidia Provides Update on Clinical Pipeline Targeting PAH and PH-ILD*, Liquidia (Jan. 5, 2024), https://www.liquidia.com/news-releases/news-release-details/liquidia-provides-update-clinical-pipeline-targeting-pah-and-ph. Upon information and belief, participants in the ASCENT trial are administered Yutrepia[™] in dosages of 26.5 mcg to greater than 185.5 mcg for the treatment of PH-ILD. *Id*.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,357,782 UNDER 35 U.S.C. § 271(b)–(c)

- 37. UTC realleges and incorporates by reference the allegations contained in $\P 1-36$ of this Complaint as if fully set forth herein.
 - 38. Claim 1 of the '782 patent recites:

A method of treating pulmonary hypertension comprising: providing an inhalation device for treating pulmonary hypertension in a human suffering from pulmonary hypertension comprising a powder formulation of treprostinil or a pharmaceutically acceptable salt thereof and a dry powder inhaler configured to administer single event dose of the powder formulation comprising treprostinil or a pharmaceutically acceptable salt thereof, wherein the single event dose comprises at least 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 3 breaths, wherein the dry powder inhaler is configured to administer the entire single event dose in less than 5 minutes with at least 5 micrograms of treprostinil or a pharmaceutically acceptable salt thereof being inhaled per breath through coordinated actuation of the dry powder inhaler with each breath, and administering to a human suffering from pulmonary hypertension with the dry powder inhaler the single event dose comprising at least 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof in 1 to 3 breaths, wherein the human administers the entire single event dose with the dry powder inhaler in less than 5 minutes by inhaling at least 5 micrograms of treprostinil or a pharmaceutically acceptable salt thereof per breath by coordinating one actuation of the dry powder inhaler for each separate breath, and wherein administration of an additional single event dose in the same manner occurs at least 3 hours later.

- 39. Upon information and belief, Liquidia engages or intends to imminently engage in the manufacture, use, offer for sale, sale, marketing, and/or distribution of Liquidia's Yutrepia[™] (treprostinil) product and labeling prior to the expiration of the '782 patent.
- 40. Upon information and belief, the Yutrepia[™] product, and its use in accordance with and as directed by Liquidia's Prescribing Information, has and will continue to literally infringe, or infringe under the doctrine of equivalents, one or more claims of the '782 patent.
- 41. Yutrepia[™] is an inhalation dry powder formulation with an active ingredient treprostinil indicated for the treatment of pulmonary hypertension, and specifically PAH and PH-ILD.
- 42. Upon information and belief, Liquidia promotes, suggests, and instructs the use of Yutrepia[™] in dosages of at least 15 mcg to 90 mcg per treatment session over one to three breaths.
- 43. For example, when used according to the Prescribing Information, patients that are prescribed Yutrepia[™] will use an accompanying inhalation device to administer a dosage of treprostinil in capsule strengths ranging from 26.5 mcg to 106 mcg over one to two breaths resulting in a dose delivered of 15.1 mcg to 75.7 mcg of treprostinil.
- 44. Upon information and belief, Liquidia promotes, suggests, and instructs the administration of Yutrepia[™] in less than five minutes. For example, the Instructions for Use disclose that each Yutrepia[™] capsule "must be inhaled within 5 minutes."

- 45. Upon information and belief, Liquidia promotes, suggests, and instructs the use of Yutrepia[™] through administration of a single dose via an inhalation device over 1 to 3 breaths, with additional doses occurring at least 3 hours later. For example, the Prescribing Information describes administration of Yutrepia[™] through an accompanying inhalation device that is configured to administer a single dose of treprostinil over two breaths. The Prescribing Information also discloses a minimum recommended dosing interval of four hours.
- 46. Accordingly, at least physicians and healthcare providers who prescribe and administer, and patients who use Yutrepia[™] as directed by the Prescribing Information and/or Instructions for Use will directly infringe the claims of the '782 patent, including at least claim 1.
- 47. Upon information and belief, Liquidia actively induces infringement of the '782 patent, including at least claim 1, under 35 U.S.C. § 271(b). Upon information and belief, Liquidia has had knowledge of the '782 patent since its issuance, but no later than the filing of this Complaint. Liquidia has had knowledge of the '782 patent and/or was willfully blind to its existence and, with the specific intent to encourage infringement, instructs patients, physicians, and healthcare providers to use Yutrepia[™] in dosages of at least 15 mcg to 90 mcg per treatment session. The Prescribing Information directs the use of a dosing regimen that results in infringement of the claim of the '782 patent, including at least claim 1.

- 48. Upon information and belief, Liquidia contributorily infringes at least claim 1 of the '782 patent under 35 U.S.C. § 271(c) by manufacturing, offering to sell, and selling Yutrepia[™] for use to treat PH in dosages of at least 15 to 90 mcg per session, which are not suitable for any substantial noninfringing use.
- 49. Upon information and belief, Liquidia knowingly and intentionally instructs and will knowingly and intentionally instruct physicians, health care providers, and/or patients to use Yutrepia[™] in accordance with the Prescribing Information in a manner that constitutes infringement of the '782 patent with the requisite intent and knowledge under 35 U.S.C. § 271(b) and (c).
- 50. Liquidia's actions constitute infringement of the '782 patent, including actively inducing infringement of the '782 patent and contributing to the infringement of the '782 patent by others. As a result of Liquidia's actions, UTC has suffered harm and is entitled to recover damages in accordance with 35 U.S.C. §§ 271, 281, and 284.
- 51. Upon information and belief, in advance of FDA approval, Liquidia is currently manufacturing, offering to sell, promoting and/or importing its Yutrepia[™] product in the United States.
- 52. The Yutrepia[™] product and/or its use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the '782 patent.
- 53. Upon information and belief, Liquidia has acted and/or is continuing to act despite an objectively high likelihood that its actions constituted infringement of a valid patent, and knew or should have known of that objectively high risk at least as early as the

June 14, 2022 issuance of the '782 patent. Thus, upon information and belief, Liquidia's infringement of the '782 patent has been, and continues to be, knowing, intentional, and willful, thereby entitling UTC to enhanced damages and reasonable attorneys' fees and costs under 35 U.S.C. § 284.

- 54. Upon information and belief, Liquidia has acted without a reasonable basis for believing that it would not be liable for infringement of the '782 patent, rendering this case exceptional under 35 U.S.C. § 285.
- 55. UTC has and will be substantially and irreparably damaged if any and all of Liquidia's activities that infringe the '782 patent are not enjoined by this Court. Liquidia's acts of infringement of the '782 patent have caused and will continue to cause UTC immediate and irreparable harm unless such infringing activities by Liquidia, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting in concert, participation, or privity with them, and their successors and assigns are enjoined by this Court pursuant to 35 U.S.C. § 283. UTC does not have an adequate remedy at law.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,357,782

- 56. UTC realleges and incorporates by reference the allegations contained in ¶¶ 1–55 of this Complaint as if fully set forth herein.
- 57. Upon information and belief, Liquidia intends to imminently manufacture, market, sell, offer to sell and/or import its Yutrepia[™] product as early as May 24, 2025, and will launch Yutrepia[™] "as soon as possible" after receiving final FDA approval.

- 58. Liquidia's submission of its NDA to the FDA, subsequent FDA approval, coupled with Liquidia's activities in support of its manufacture, importation, and launch of its Yutrepia[™] product for commercial sale in the United States, creates an actual, immediate, and real controversy within the Declaratory Judgment Act regarding Liquidia's active inducement and/or contribution to the infringement of, valid and enforceable claims of the '782 patent before its expiration in violation of 35 U.S.C. § 271 (b) or (c). Liquidia's actions have created in UTC a reasonable apprehension of irreparable harm and loss resulting from Liquidia's imminently infringing activities.
- 59. The use of the Yutrepia[™] product and/or its manufacture as disclosed in Liquidia's Prescribing Information and Instructions for Use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the '782 patent. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.
- 60. Upon information and belief, Liquidia has acted and/or is continuing to act despite an objectively high likelihood that its actions constituted infringement of a valid patent, and knew or should have known of that objectively high risk at least as early as the June 14, 2022 issuance of the '782 patent. Thus, upon information and belief, Liquidia's infringement of the '782 patent has been, and continues to be, knowing, intentional, and willful, thereby entitling UTC to enhanced damages and reasonable attorneys' fees and costs under 35 U.S.C. § 284.

- 61. Upon information and belief, Liquidia has acted without a reasonable basis for believing that it would not be liable for infringement of the '782 patent, rendering this case exceptional under 35 U.S.C. § 285.
- 62. UTC will be substantially and irreparably damaged and harmed if Liquidia's infringement of the '782 patent is not enjoined by this Court. Liquidia's acts of infringement of the '782 patent have caused and will continue to cause UTC immediate and irreparable harm unless such infringing activities by Liquidia, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting in concert, participation, or privity with them, and their successors and assigns are enjoined by this Court pursuant to 35 U.S.C. § 283. UTC does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, UTC prays for judgment against Liquidia and respectfully requests the following relief:

- A. A judgment declaring that Liquidia has and will infringe either literally, or under the doctrine of equivalents, actively induce infringement of, and/or will contribute to the infringement by others of at least one claim of the '782 patent under 35 U.S.C. § 271(b)–(c);
- B. A judgment declaring that the making, using, selling, offering for sale, or importing into the United States of Liquidia's Yutrepia[™] product, or any product that infringes one or more claims of the '782 patent prior to its expiration date, will infringe,

actively induce infringement of, and contribute to the infringement by others of the '782 patent;

- C. An order enjoining Liquidia and its respective officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting on behalf of or in active concert or participation therewith, from further infringement of the '782 patent;
- D. Any available equitable or injunctive relief to prevent the commercial manufacture, use, offer to sell, or sale of Yutrepia[™] pursuant to 35 U.S.C. § 283, 28 U.S.C. § 2202, and Fed. R. Civ. P. 65;
- E. An award of damages sufficient to compensate UTC for Liquidia's infringement under 35 U.S.C. § 284;
- F. A declaration that Liquidia's infringement of the '782 patent has been willful and deliberate, and an increase to the award of damages of three times the amount found or assessed by the Court, in accordance with 35 U.S.C. § 284;
- G. A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding UTC its attorney's fees;
 - H. An award of costs and expenses in this action to UTC; and
 - I. Such other and further relief as the Court deems just and appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, UTC respectfully demands a trial by jury on all triable issues.

This the 9th day of May, 2025.

SMITH, ANDERSON, BLOUNT, DORSETT, MITCHELL & JERNIGAN, L.L.P.

/s/ Christopher G. Smith

Christopher G. Smith

N.C. State Bar No. 22767

David A. Pasley

N.C. State Bar No. 52332

Post Office Box 2611

Raleigh, North Carolina 27602-2611

Telephone: (919) 821-6745 Email: csmith@smithlaw.com dpasley@smithlaw.com

William C. Jackson*
D.C. Bar. No. 475200
Goodwin Procter LLP
1900 N Street, NW
Washington, DC 20001
Telephone: (202) 346-4000

Email: WJackson@goodwinlaw.com

Douglas H. Carsten*
CA. Bar No. 198467
McDermott Will & Emery LLP
12636 High Bluff Drive, Suite 325
San Diego, CA 92130
Telephone: (619) 467-1802

Email: Dcarsten@mwe.com

*Notice of special appearance forthcoming

Attorneys for United Therapeutics Corporation